Securities and Exchange Commission Office of International Corporate Finance 100 F Street, N.E., Mail Stop 3628 Washington DC 20549 USA

12g-3-2(b) Exemption File N°.82-34953

31 August 2007



Dear Sir or Madam,

SUPPL

Enclosed is information Ipsen:

- made or is required to make public under French law;
- filed or is required to file with and which is made public by Euronext Paris; or
- distributed or is required to distribute to its shareholders.

This information is being furnished under Paragraph (b)(1)(i) of Rule 12g-3-2 of the Securities Exchange Act of 1934; as amended (the *Exchange Act*), with the understanding that such information and documents will not be deemed "filed" with the U.S. Securities and Exchange Commission or otherwise subject to the liabilities of Section 18 of the Exchange Act, and that neither this letter or the furnishing of such documents and information shall constitute an admission for any purpose that Ipsen is subject to the Exchange Act.

Yours sincerely,

Claire Giraut
Executive Vice President,

Chief Financial Officer

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# Press release

# Somatuline® Depot receives marketing approval in the United States for the treatment of acromegaly

# Somatuline® Depot becomes the first product originating from Ipsen's R&D to be approved by the FDA and marketed globally<sup>1</sup>

Paris (France), 31 August 2007 - Ipsen (Euronext: FR0010259150; IPN) today announced that the U.S. Food and Drug Administration (FDA) has approved for marketing Somatuline® Depot (lanreotide) Injection 60, 90 and 120 mg in the United States.

Somatuline® Depot is indicated for the long-term treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. Somatuline® Depot will be available in a pre-filled syringe eliminating any need for reconstitution and thus enabling freedom of easy administration to patients.

In October 2006, Ipsen granted to Tercica the development and commercialization rights for Somatuline® Depot in the US and Canada. At the same time, Ipsen acquired a 25% stake in Tercica on a non-diluted basis. According to the terms of the agreement, the FDA approval of Somatuline® Depot triggers a €30 million milestone payment that Tercica will pay to Ipsen by issuing a convertible bond (converted into Tercica common stock at a conversion price of €5.92). Tercica will simultaneously issue an additional \$15 million convertible bond to Ipsen (converted into Tercica common stock at a conversion price of \$7.41) which will be paid in cash to Tercica.

Tercica now expects to launch Somatuline® Depot in the United States in the fourth quarter 2007.

Jean-Luc Bélingard, Chairman and CEO of Ipsen said "We are very proud to be able to announce today that a product originated from Ipsen's R&D will be available globally. This is Ipsen's first ever FDA approval, a major achievement made possible thanks to the outstanding dedication and commitment of our teams. We feel confident that our partner Tercica will market Somatuline® Depot very successfully by offering to patients suffering from acromegaly a new treatment option that has been proven to be effective, and very convenient to use. With Somatuline®, Increlex®, NutropinAq® and its very rich pipeline of research products, Ipsen confirms its strong commitment to the progress of endocrinology worldwide."

## About acromegaly

Acromegaly is a disorder caused by the over-production of growth hormone usually by a benign tumour of the anterior pituitary gland. Acromegaly occurs in approximately 60 people per million of population. In acromegaly patients, the pituitary gland releases too much growth hormone ("GH") into the bloodstream, the GH then triggers the liver to produce IGF-1, which in turn directly stimulates bone and tissue growth. The most common signs and symptoms of this serious condition include: enlarged hands, feet, and head, facial changes such as bulging forehead, enlarged lower jaw, tongue and lips, wider spacing between teeth,

<sup>&</sup>lt;sup>1</sup>Somatuline<sup>®</sup> Depot is marketed outside the United States of America as Somatuline<sup>®</sup> Autogel<sup>®</sup> with the exception of Japan, where the product is developed by Ipsen's partner Teijin and is currently in phase II clinical trial.



enlarged heart, liver, kidneys, spleen and other organs, joint pain and fatigue, reduced sex drive and loss of concentration.

About the approval for marketing

The summary of the approval for marketing will be accessible at <a href="http:///www.fda.gov">http:///www.fda.gov</a>
This decision follows the filing by Ipsen of a New Drug Application (NDA) for Somatuline®
Depot in the USA in December 2006. The effect of Somatuline® Depot on reducing GH and IGF-levels and control of symptoms in patients with acromegaly was studied in two long-term, multiple-dose, randomized multicenter studies performed in the United States and in Europe. Somatuline® Depot demonstrated its ability to decrease the levels of GH and IGF-1 in the majority of patients over a one year period.

About Somatuline® Depot and Somatuline® Autogel®

Somatuline® Depot (also marketed as Somatuline® Autogel® outside the USA) is a sustained-release formulation for injection containing lanreotide, a somatostatin analogue (a hormone that inhibits the release of growth hormone). Somatuline® was initially developed and continues to be used mainly in the treatment of acromegaly, a disorder caused by the over-production of growth hormone or prolactin due to a benign tumour of the anterior pituitary gland. This product subsequently underwent further development in Europe in the treatment of symptoms associated with neuroendocrine tumours (particularly of a carcinoid type). Ipsen believes that the Somatuline® Autogel® formulation, to which it holds the patent, represents a major technological advance. As far as the Group is aware, this represents the first semi-solid formulation for injection without any excipient, since the active substance itself controls the sustained release. Somatuline® Autogel® releases the active substance with no excipient other than water over a period of at least 28 days, thus requiring just one injection per month compared with the two or three injections previously necessary. This product is presented in a pre-filled syringe for easy administration.

# Active substance

The active substance in Somatuline® and Somatuline® Autogel® is lanreotide, which inhibits the growth and secretion of several endocrine, exocrine and paracrine functions. It is particularly effective in inhibiting the secretion of growth hormone.

#### Indications

Somatuline® is used primarily in the treatment of acromegaly when circulating levels of growth hormone remain high despite surgery or radiotherapy. Somatuline® inhibits growth hormone release and thus controls the therapeutic and relieves the symptoms associated with elevated levels of this hormone.

#### Intellectual property

Ipsen holds an exclusive worldwide license granted by Tulane University (United States) to manufacture, use and market the active substance in Somatuline® (lanreotide) and is the direct holder of the patent covering the Somatuline® Autogel® or Depot formulation. The Group holds patents to the Somatuline® Autogel® formulation, which are set to expire in 2015 in Europe and in the United States. The patent protecting the active substance expired in 2006 in the United States and expired in December 2005 in Europe, except in Belgium, France, Italy, Luxembourg and the United Kingdom where additional certificates of protection remain valid until 2009.

#### Marketing

Somatuline® Autogel® is marketed in almost 60 countries (including 26 in Europe) by Ipsen for the treatment of acromegaly and neuroendocrine tumours or acromegaly alone. Somatuline



had sales of €92 million in 2006, out of which 68% were generated in the Major Western European Countries (France, Germany, Italy, Spain, United Kingdom). Somatuline® Autogel® accounted for 86% of total sales of this product. Somatuline® and Somatuline® Autogel® are prescribed mainly by endocrinologists, gastroenterologists, oncologists, surgeons and intensive care specialists.

#### About Ipsen

Ipsen is an innovation driven international specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,000. The company's development strategy is based on a combination of products in targeted therapeutic areas (oncology, endocrinology and neuromuscular disorders) which are growth drivers, and primary care products which contribute significantly to its research financing. This strategy is also supported by an active policy of partnerships. The location of its four Research and Development centres (Paris, Boston, Barcelona, London) gives the Group a competitive edge in gaining access to leading university research teams and highly qualified personnel. In 2006, R&D expenditure was €178.3 million, i.e. 20.7% of consolidated sales, which amounted to €861.7 million while total revenues amounted to €945.3 million (in IFRS). 700 people in R&D are dedicated to the discovery and development of innovative drugs for patient care. Ipsen's shares are traded on Segment A of Eurolist by Euronext<sup>TM</sup> (stock code: IPN, ISIN code: FR0010259150). Ipsen's shares are eligible to the "Système à Règlement Différé" ("SRD") and the Group is part of the SBF 250 index. For more information on Ipsen, visit our website at <a href="https://www.ipsen.com">www.ipsen.com</a>.

### Forward-looking statements

The forward-looking statements and targets contained herein are based on Ipsen's management's current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. Moreover, the Research and Development process involves several stages at each of which there is a substantial risk that the Group will fail to achieve its objectives and be forced to abandon its efforts in respect of a product in which it has invested significant sums. Therefore, the Group cannot be certain that favourable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. Ipsen expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. Ipsen's business is subject to the risk factors outlined in its information documents filed with the French Autorité des marchés financiers.

#### About Tercica

Tercica is a biopharmaceutical company committed to improving endocrine health by partnering with the endocrine community to develop and commercialize new therapeutics for paediatric and adult growth disorders, and for adult metabolic disorders. For further information on Tercica, please visit www.tercica.com.

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